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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/055,775	01/23/2002	Steven Mark Eker	SRI/4578-2	8753

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EXAMINER

LY, CHEYNE D

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 06/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/055,775	Applicant(s) EKER ET AL.	
	Examiner Cheyne D. Ly	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2005, 7/26/2004; 10/29/04
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-111 is/are pending in the application.
- 4a) Of the above claim(s) 25-98 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 and 99-111 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-111 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' arguments filed October 29, 2004 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.
2. Claims 1-24 and 99-111 are examined on the merits.
3. NON-FINAL OFFICE ACTION.

INVENTORSHIP

4. Specific to the petition to correct inventorship, filed January 16, 2004, it appears that a party required by 37 CFR 1.48(a)(2) to submit a statement of facts may not be willing to submit such statement, applicant should consider either: a) submission of a petition under 37 CFR 1.183 to waive that requirement if the original named inventor(s) has assigned the entire right and interest to an assignee who has given its consent to the requested inventorship correction, MPEP § 201.03, Statement of Lack of Deceptive Intention, or b) refiling the application (where addition is needed under 37 CFR 1.53(b) with a new oath or declaration and any necessary petition under 37 CFR 1.47, or where only deletion is needed, either under 37 CFR 1.53(b) utilizing a copy of a prior oath or declaration under 37 CFR 1.63(d)(1)(iv), or under 37 CFR 1.53(d))(design applications only), thereby eliminating the need for a 37 CFR 1.48 request.

Art Unit: 1631

5. The statement of facts by inventors to be added does not explicitly state that the inventorship error occurred without deceptive intent on his or her part or cannot be construed to so state.

6. It is noted that statements of facts has been submitted for the instant inventors Steven Eker and Patrick Lincoln. However, the 37 CFR 1.48(a)(2) requires the statement from each inventor being added.

SEQUENCE COMPLIANCE

7. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2). See, for example, page 37, (16). However, this application fails to comply with the requirements of 37 CFR § 1.821 through 1.825 because page 37, (16), contain amino acid sequences with sequence lengths that are equal to or greater than 4 amino acid molecules and these sequences do not have SEQ ID Nos cited along with each sequence in the specification. Applicants are also reminded that a CD-ROM sequence listing submission may replace the paper and computer readable form sequence listing copies. Applicant(s) are required to submit a new computer readable form sequence listing, a paper copy for the specification, statements under 37 CFR § 1.821(f) and (g), if there is a need to list additional sequences in the listing. Applicant(s) are given the same response time regarding this failure to comply as that set forth to respond to this office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

CLAIM REJECTIONS - 35 U.S.C. § 112, SECOND PARAGRAPH

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-24 and 99-111 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claim 1, line 1, recites the limitation of “for evaluating at least one metabolic pathway” which cause said claim to be vague and indefinite because the metes and bounds of the claim are not clear. For example, lines 3-8 of claim 1 does not recite any limitations directed to metabolic pathway. Therefore, it is not clear whether the preamble (lines 1-2) or the rest of the claim (lines 3-8) controls the metes and bounds of claim 1. The same issue is present in claims 12, 23, 99, 105, 106, and 107. Claims 2-11, 13-22, 24, 100-104, 108-111 are rejected for being dependent from claim 1, 12, 23, 99, 105, 106, and 107.

CLAIM REJECTIONS - 35 USC § 101

11. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

12. Claims 1-24 and 99-111 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory algorithm type subject matter.

RESPONSE TO ARGUMENTS

13. On page 022, Applicant argues that the claims have been amended to recite the limitation “for evaluating at least one metabolic pathway.” Therefore, the claimed invention is directed to statutory subject matter because “evaluating a metabolic pathway produces a useful, concrete and tangible results.” Applicant’s argument has been fully considered and found to be unpersuasive because the limitation “for evaluating at least one metabolic pathway” does not cause the claim as a whole to overcome the instant rejection. For example, claim 1 recites “evaluating at least one metabolic pathway” for “generating a symbolic model”. A reasonable interpretation of claim 1 is that the “metabolic pathway” is a data representation that is being manipulated to generate a “symbolic model.” Further, the limitation of substrates and product have been reasonably construed as data representation being manipulated by the claimed method. As presented, the claims do not produce a concrete and tangible result. Therefore, the claim amendment has not cause the claimed invention to overcome the instant rejection as discussed below.

BASIS OF REJECTION

14. Claims 1-22, 99-104, and 107-111 rejected because said claims are directed to a method for modeling data without any physical alteration step, which is considered to be non-statutory subject matter. “For example, a computer process that simply calculates a mathematical algorithm that models noise is nonstatutory. However, a claimed process for digitally filtering noise employing the mathematical algorithm is statutory.” (MPEP § 2106 (IV)(B)(2) (b), part ii). Similar to the nonstatutory example above, the instant invention comprises algorithmic steps for modeling data without any physical alteration resulted from

said analysis or modeling steps.

15. “For example, a computer process that simply calculates a mathematical algorithm that models noise is nonstatutory. However, a claimed process for digitally filtering noise employing the mathematical algorithm is statutory.” (MPEP § 2106 (IV)(B)(2) (b), part ii). The step of filtering noise is controlled by the results generated from the data manipulation. The difference between the claimed invention and the citation above is that the instant claims recite limitations directed to data manipulation without any limitation which could reasonably be construed as controlling any physical steps resulted from said data manipulation.

16. Specific to claims 23, 24, 105, and 106 the recite a computer-readable medium having a plurality of instructions. The plurality of instructions has been considered to be nonfunctional descriptive material. “When nonfunctional descriptive material is recorded on some computer-readable medium, it is not statutory since no requisite functionality is present to satisfy the practical application requirement. Merely claiming nonfunctional descriptive material stored in a computer-readable medium does not make it statutory. (MPEP § 2106 (IV)(B)(1))

CLAIM REJECTIONS - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. Claims 1-6 and 11 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Goto et al. (1998).

19. Goto et al. discloses the modeling (symbolic) of metabolic pathways as directed to the network of chemical reactions involving chemical compounds and catalyzed by enzymes (page 591, column 2, third paragraph). The chemical substances include substrates, products, inhibitors, cofactors, and effectors (page 592, last paragraph). Figure illustrates the identified set of precursor substrates and the produced target products (page 593). Goto et al. identifies the compounds and enzymes which are known to interaction in chemical reactions (page 592, column 2, last paragraph), as in instant claim 1.

20. The set of precursor substrates in Table 1 has been reasonably construed as the minimal set for the chemical reaction, as in instant claim 2.

21. KEGG comprises 2822 chemical reactions (sets) (page 594, Table 1), wherein Figure 1 is an example of one of the reactions, as in instant claims 3, 4, and 11.

Art Unit: 1631

22. The total number of entries is 3603, which includes deleted and transferred entries, so the number of meaningful ENZYME entries and REACTION fields is 3303. (page 594, column 2, 1st paragraph), as in instant claims 5 and 6.

CLAIM REJECTIONS - 35 USC § 103

23. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

24. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

25. Claims 1-6, 7, 8, 11-18, 20-24, and 99-106 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goto et al. (1998) taken with Akutsu et al. (2000).

RESPONSE TO ARGUMENT

26. On pages 023-024, Applicant's summary of Akutsu et al. has been noted. Specific to the Applicant's pointed discussion by Akutsu et al., said pointed to discussion is not persuasive because it is not clear what specific limitation Applicant has alleged to be not described by Akutsu et al. It is further noted that Akutsu states that the proposed method are difficult to be applied to real data. However, the type of data required by the claimed invention has been reasonably construed as the type of the data utilized by the method of Akutsu et al. because the claimed invention is directed to "symbolic model."

27. Applicant argues that Akutsu et al. does not disclose the limitation of "a symbolic model for evaluating a metabolic pathway which is represented by a Boolean function."

Applicant's argument has been fully considered and found to be unpersuasive. Applicant's summary of Akutsu et al. on page 023 has been noted. It is further noted that Applicant acknowledges (page 023, 3rd paragraph) that the model of Akutsu et al. "can be considered as a combination of the Boolean network and qualitative rules and embedded in network structures." Further, the specification discloses the "symbolic model can include a Boolean function that returns a predetermined value... Such a function can be expressed in if-then-else normal form" (page 2, lines 6-9). Applicant's acknowledgement supports that Akutsu et al. does disclose the argued limitation as defined by the instant specification. Therefore, Goto et al., a newly cited, and Akutsu et al. render the claims obvious over the prior art.

BASIS FOR REJECTION

28. Goto et al. describes the limitations to claims 1-6 and 11 as discussed above.

29. However, Goto et al. does not describe the limitation of a symbolic model comprising “a Boolean function.”

30. Akutsu et al. discloses a method and computer program for generating network models and metabolic pathways for molecular processes using Boolean functions wherein the data are captured from microarray hybridization chemical reactions (page 727, Abstract etc., Introduction §, columns 1-2). The inference of S-systems is directed to the Michaelis-Menten equation, which expresses enzymatic reactions involving one substrate and one product (page 730, column 2, Inference of S-systems §, lines 5-9). Further, The method generates values (predetermined) from the Boolean function corresponding to targets (Tables 1 and 2). Akutsu et al. proves that $O(\log n)$ expression patterns are necessary and sufficient to identify the underlying Boolean network of n genes correctly with high probability if the maximum indegree is bounded (relationship) (page 727, column 2, lines 5-9). The Boolean network is identified based on input patterns (received) wherein the Boolean network $G(V,F)$ (variables) consists of a set $V=\{V_1, \dots, V_n\}$ of nodes representing genes and a list of Boolean functions $F=(f_1, \dots, f_n)$. An expression pattern is a function of V to $\{0,1\}$ (at least one prime implicates) (page 728, column 1, Identification of Boolean networks with noises §). The method of Akutsu et al. has been implemented on SSYS-1 using a Sun Ultra-2 Workstation

Art Unit: 1631

and commercial software SOPT (page 731, columns 1-2, Results on S-systems §), as in instant claims 7, 12, 21-24, 99, 105, and 106.

31. Goto et al. in view of Akutsu et al. as cited above describe the limitations of claims 13 and 14.

32. An expression pattern is a function of V to $\{0,1\}$ (at least one prime implicates) (page 728, column 1, Identification of Boolean networks with noises §), as in instant claims 15-17, 100, and 101.

33. The code for the method of Akutsu et al. is in the if-then-else normal form (page 728, column 2, lines 31-44) comprising a fixed constant (page 729, column 1, lines 1-4), which is used for defining nodes (fixed point) on a network model (page 729, column 1, lines 18-25), as in instant claims 8 and 20.

34. It is noted that the inclusion of Akutsu et al. (1999) is not being used as prior art, but only to expand on the citation of a reference (Akutsu et al. (1999)) by Akutsu et al.

35. Akutsu et al. (1999) describes wiring diagrams comprising paths (binary) for a set of nodes (expression state) as defined by the INPUT/OUTPUT values (page 20, Figure 1), as defined by page 36 of the instant specification, as in instant claim 18 and 102.

36. The Boolean network is identified based on input patterns (received) wherein the Boolean network $G(V,F)$ (variables) consists of a set $V=\{V_1, \dots, V_n\}$ of nodes representing genes and a list of Boolean functions $F=(f_1, \dots, f_n)$ (page 728, column 1, Identification of Boolean networks with noises section), as in instant claims 103 and 104.

37. Akutsu et al. describes “there is much room for improvements in the proposed methods.” For example, Akutsu et al. suggests modification to the method to monitoring mRNA and protein (page 733, column 1, lines 21-28). An artisan of ordinary skill in the art at the time of the instant invention would have been motivated by the improvement described by Akutsu et al. to modified said method with the method describe by Goto et al. as directed to DNAs, RNAs, and proteins (page 591, Abstract etc.). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to use a method and computer program for generating network models and metabolic pathways for molecular processes using Boolean functions as describe by Goto et al. and Akutsu et al.

CONCLUSION

38. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547. The USPTO’s official fax number is (571) 273-8300.

39. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO’s Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent

Art Unit: 1631

number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

40. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

41. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

42. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

C. Dune Ly
6/16/05



 6/20/05
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER